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Charles N J Ruggiero
Ohlandt Greeley Ruggiero & Perle
10th Floor
One Landmark Square
Stamford, CT 06901-2682

| EXAMINER | |
|---|---|
| OSTRUP, CLINTON T | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/522,073 | MATARASSO, HASDI | |
| | Examiner | Art Unit | |
| | Clinton Ostrup | 3771 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☒ Claim(s) *1-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-27 are pending in this application.

### *Priority*

The examiner acknowledges this application was filed as a United States National Phase Application of International Application Serial No. PCT/IL03/00599 filed July 22, 2003, which claims priority to United Spates Provisional Application No. 60/397,042 filed July 22, 2002.

### *Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it makes claims foreign priority claims to an International Application which designated the United States. Therefore, it is not a foreign application. Moreover, there is no mention in the Declaration of the previously filed US Provisional Application No. 60/397,042 filed July 22, 2002, which the International Application designates as a priority document.

Appropriate correction is required.

### *Drawings*

The drawings are objected to because: Figures 1 & 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Evidence that these figures are prior art is located on page 7, lines 21-23 wherein applicant has admitted both 1A and 1B as prior art. Corrected drawings in

compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are also objected to because: Figures 7A, 7B, 7D and 8A contain handwritten alterations and characters. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

The disclosure is objected to because of the following informalities: There are numerous typographical and grammatical errors and in the specification. The specification also uses inconsistent terminology to refer to characters which designate parts in the drawings. Example of typographical errors can be seen on page 6, lines 25-26 and page 7, line 2. Examples of grammatical errors can be seen on page 7, line 4 and line 8. Examples of inconsistent terminology used to designate characters can be seen on page 10, line 2, 3, 8 which all refer to character "20" by different terms. Another example of this inconsistent terminology can be found on page 10, lines 18, 21-22, and 27 which all refer to character "22" by different terms. The specification is replete with this type of inconsistent terminology for designated characters and applicant is reminded to be consistent in their terminology.

Moreover, the specification is not consistent in the capitalization of Venturi. If applicant desires Venturi to be capitalized, it should be consistent throughout the specification and the claims.

Applicant should go through the specification and correct the typographical and grammatical errors and change the terminology used to designate the characters to be consistent through out the specification, without adding new matter.

As a final note, the specification also lacks a period at the bottom of on page 8.

***Claim Objections***

Claims 1-27 are objected to because of the following informalities:

In the claims, when the term "the" or "said" is used, the word or phrase following the term "the" or "said" must have proper antecedent basis. The terms "the" and "said" appear numerous times in the claims without proper antecedent basis for the limitations following the terms "the" and "said."

For example, Claim 1 recites the limitation "the apparatus" in line 2; however, there is insufficient antecedent basis for this limitation in the claim. Applicant has provided antecedent basis for "a respiratory aid apparatus" and they are reminded to be consistent in their terminology. Claim 1 also recites the limitations "the user's" in line 4; "the inlet" in line 10, "the second end" in line 12; "the source of [a] high pressure respiratory gas" in lines 14-15 and "said inlet" in line 15 all without proper antecedent basis.

Claims 2-27 are objected to for reasons analogous to those of claim 1.

Claims 1-27 are also objected to because they are not consistent in the capitalization of Venturi. If applicant desires Venturi to be capitalized, it should be consistent throughout the claims. For example, claim 1 capitalizes Venturi; whereas claim 19 does not capitalize Venturi. Since, it is unclear if applicant intends to capitalize Venturi, and the specification is also inconsistent in the capitalization of Venturi, all claims are objected to until they are consistent.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-13 and 27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it because it is unclear what constitutes "a low cross-section flexible tubing."

Claims 12, 13, and 27 are rejected because they provide for the use of an apparatus, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 is confusing because if is redundant. The Venturi device is already defined in the apparatus of claim 1, thus applicant's claim where the Venturi devices are "defined in claim 1" is redundant and makes the claim ambiguous.

Claim 19 is rejected for analogous reasons to that of claim 14.

Claim 21 is confusing because it is unclear what is meant by "to the user head."

Claim 22 is confusing because it is unclear what is meant by "the Venturi device is having an end open...."Does the Venturi device have an open end?

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12-20 and 22-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 10/565,363.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to respiratory aid apparatuses using the same device. Although claims 1-30 of 10/565,363 are drawn to a nasal interface,

whereas claims 1-27 are drawn to broader user interface, the claims are not patentably distinct from one another because a nasal interface (species) anticipates the broader user interface (genus).

Moreover, claims 14 & 19-21 claimed instantly are drawn to a nasal interface.

The limitations of claims 1 are found in claim 1 of 10/565,363. The limitations of claim 2 are found in claim 2 of 10/565,363. The limitations of claim 3 are found in claim 3 of 10/565,363. The limitations of claim 4 are found in claim 4 of 10/565,363. The limitations of claim 5 are found in claim 5 of 10/565,363. The limitations of claim 6 are found in claim 6 of 10/565,363. The limitations of claim 7 are found in claim 7 of 10/565,363. The limitations of claim 8 are found in claim 8 of 10/565,363. The limitations of claim 9 are found in claim 9 of 10/565,363. The limitations of claim 10 are found in claim 10 of 10/565,363. The limitations of claim 12 are found in claim 11 of 10/565,363. The limitations of claim 13 are found in claim 12 of 10/565,363. The limitations of claim 14 are found in claim 13 of 10/565,363. The limitations of claim 15 are found in claims 15 of 10/565,363. The limitations of claim 16 are found in claim 16 of 10/565,363. The limitations of claim 17 are found in claim 17 of 10/565,363. The limitations of claim 18 are found in claim 18 of 10/565,363. The limitations of claim 19 are found in claim 19 of 10/565,363. The limitations of claim 20 are found in claim 23 of 10/565,363. The limitations of claim 22 are found in claim 25 of 10/565,363. The limitations of claim 23 are found in claim 26 of 10/565,363. The limitations of claim 24 are found in claim 27 of 10/565,363. The limitations of claim 25 are found in claim 28 of

10/565,363. The limitations of claim 26 are found in claim 29 of 10/565,363. The limitations of claim 27 are found in claim 30 of 10/565,363.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-2, 4-5, 7, 11-13, 15-17 and 22-27, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Sherrod (5,979,444).**

Regarding claim 1, Sherrod discloses a respiratory aid apparatus (Figures 1 and 3) for administrating a controlled flow of respiratory gas to a user airways, the apparatus comprising: a source of a high pressure respiratory gas(18); a user interface unit located proximal to the user's air intake organs (30)in fluid communication with the user airways, the user interface unit includes at least one Venturi device (28), the Venturi device comprises: a hollow member, defining a central space (46), having a first end open to surrounding ambient air (36) and a second open end directed toward the user airways (64); and a first inlet port opening into said central space(44), the inlet is configured to direct compressed gas entering said central space toward the second end; and a low cross-section flexible tubing (20 & 24) connecting between the source of high pressure respiratory gas and said inlet of said Venturi device. See: col. 2, lines 3-35; col.3, line 20 – col. 4, line 58; col. 5, line 18 col. 6, line 50; and figures 1-3.

Sherrod discloses air as a respiratory gas and oxygen as the bottled gas, thus meeting the limitations of claims 2, 4 & 5. Sherrod discloses a pressure regulator (90) as a means for selectively alternating air pressure of air dispensed by the oxygen bottle and discloses that a mask (30) is used to deliver the gas to a user, thus meeting the limitations of claim 7 and 11. Regarding claim 12, Sherrod discloses a Venturi device comprising a second inlet port opening (48) into said central space and wherein said second inlet is configured to direct compressed gas entering the central space toward the first end for assisting removal of air from the user's airways Regarding claim 13, Sherrod discloses a regulator valve (22) for directing the compressed air alternately to the first inlet port during inhalation phase and to the second inlet port during exhalation phase.

Regarding claim 15, Sherrod discloses a gas delivery user unit (Figures 1 & 3), to be located proximal to the user's air intake organs, in fluid communication with the user airways, the user interface unit (30) includes at least one Venturi device (28), the Venturi device comprises: a hollow member, defining a central space (46), having a first end open to surrounding ambient air (36) and a second open end directed toward the user airways (64); and a first inlet port (44) connectable via thin tubing (20 & 24) to a source of high pressure respiratory gas (18), opening into said central space, the inlet is configured to direct compressed gas entering said central space toward the second end.

Regarding claim 16, Sherrod discloses the gas delivery user interface unit (30) comprises a second inlet port (48) opening into said central space, wherein said second

inlet is configured to direct compressed gas entering the central space toward the first end for assisting removal of air from the user's airways. Regarding claim 17, Sherrod discloses a gas delivery user interface unit with a controllable valve (22) for directing the compressed air alternately to the first inlet port during inhalation phase and to the second inlet port during exhalation phase.

Regarding claim 22, Sherrod discloses a method for supplying a controlled pressure of respiratory gas of to a user, the method comprising: delivering a high pressure respiratory gas via a thin tubing (20 & 24) to a user interface (30) in fluid communication with the user airways, the user interface has an inlet port (44) connectable to said thin tubing; and accelerating the high pressure respiratory gas upon entering the user interface by means of a Venturi device (28) located at the inlet port of the user interface, the Venturi device is configured to direct flow of compressed air toward the user airways, the Venturi device has an end open to surrounding ambient air (36); thereby pumping ambient air into the user interface. The Sherrod reference discloses the respiratory gas as air and using a pressure regulator to control the pressure of the high pressure respiratory gas delivered to the user interface.

Regarding claims 23-27, Sherrod discloses a method of using the device and that the device has a regulator valve (22) that stops the delivery of high pressure respiratory gas during the exhalation phase. Sherrod discloses a method of using a Venturi device (28) with an additional inlet configured to direct compressed air toward the end open to ambient air and wherein the method further comprising delivering the high pressure respiratory gas to said additional inlet for assisting removal of air from the

user airways during exhalation phase. Sherrod also teaches that the user interface unit is in fluid communication with a user airways and the Venturi device (28) administers a controlled pressure of air to the user.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claim 3, as best understood, is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherrod (5,979,444), as applied to claim 1 above and further in view of Hill et al., (US 2002/0096174).**

Sherrod discloses a respiratory aid apparatus as claimed in clam 1; however, Sherrod lacks the oil-less air compressor as claimed in claim 3.

Hill teaches a portable oxygen concentrator system wherein the compressor is preferably an oil-less compressor to prevent the possibility of oil or grease from entering the air flow path. See: page 3, [0036].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Sherrod's portable breathing assisting device by using an oil-less compressor, as taught by Hill et al., so as to prevent oil or grease from entering a patient's respiratory tract.

**Claims 6, 8-10 and 18, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherrod (5,979,444), as applied to claims 1 and 15 above and further in view of Boussignac (6,363,935).**

Sherrod discloses a respiratory aid apparatus as claimed in clam 1, and a gas delivery unit as claimed in claim 15; however, Sherrod lacks the specific tube size claimed in claim 6 and the sensor as claimed in claims 8-10 and 18.

The Boussignac reference teaches a Venturi device (2) of various sizes for delivering respiratory gas to a patient with a pressure sensor for detecting overpressure. The tube sizes of the device made by Boussignac overlap the sizes of the tubes as claimed in claim 6. The sensor taught by Boussignac detects if overpressure occurs in the respiratory tract of the patient, using a sensor that is located in the interface unit, thus meeting the limitations of claims 8-10 and 18. See: col. 4, lines, lines 16-18; col. 5, line 25 – col. 6, line 24 and figure 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Sherrod's respiratory aid apparatus by using the tube size and pressure sensor as taught by Boussignac in order to form a respiratory device that uses common medical tubes and prevents overpressure of the respiratory track of a patient.

**Claims 14, 19 and 21, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherrod (5,979,444), as applied to claims 1 and 15 above and further in view of Moa et al., (5,193,532) taken together with Trimble et al., (4,782,832).**

Sherrod discloses a respiratory aid apparatus as claimed in clam 1 and a gas delivery unit as claimed in claim 15; however, Sherrod lacks the dual Venturi devices and nasal adapters as claimed in claim 14, 19 & 21.

Moa et al., teach a device for assisted breathing wherein the device provides a single compact unit that is adapted to be provided with an attachment for delivering air to the nose and/or mouth. See: col. 1, lines 6-35; col. 2, lines 13-25 and figures 1-6.

Trimble et al., teaches a nasal puff assembly for delivering air to a patient using the nasal airway using small nasal puffs that can be comfortably worn by a user. The device of Trimble comprises two nasal adapters each directed to a nostril of at patient and being supported with a strap over the user's head. See: col. 2, lines 22-52 and figures 1-14.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Sherrod's respiratory apparatus by forming a compact dual breathing channel as taught by Moa et al., and using the nostril adapters as taught by Trimble et al., to form a compact, comfortably worn breathing device that has administers air to each respective nostril of a patient.

**Claim 20, as best understood, is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherrod (5,979,444), as applied to claim 15 above and further in view of Moa et al., (5,193,532) taken together with Goldstein., (5,752,510)**

Sherrod discloses a gas delivery unit as claimed in claim 15; however, Sherrod lacks the dual Venturi devices and mouthpiece as claimed in claim 20.

Moa et al., teach a device for assisted breathing wherein the device provides a single compact unit that is adapted to be provided with an attachment for delivering air to the nose and/or mouth. See: col. 1, lines 6-35; col. 2, lines 13-25 and figures 1-6.

Goldstein teaches apparatus that has a dual nosepiece and a mouthpiece for providing an air supply to a patient. Goldstein teaches that the device is useful for delivering an air supply because it provides a means for stabilizing and supporting the nasal tubes and maintains the user's lower jaw in a forward. See: col. 2, lines 15-59 and figures 1, 2, and 3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Sherrod's respiratory apparatus by forming a compact dual breathing channel as taught by Moa et al., and using the delivery unit as taught by Goldstein to form a breathing device that alleviates many sleeping disorders by providing air to a user while maintaining the user's jaw in a forward position.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Boussignac, (US 6,814,075); Boussignac, (US 6,273,087) and Watts (4,718,870) all of which are drawn to Venturi devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (571) 272-5559. The examiner can normally be reached on M-F 7:30-5 pm with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/

Examiner, Art Unit 3771

Clinton Ostrup
Examiner
Art Unit 3771

/Justine R Yu/

Supervisory Patent Examiner, Art Unit 3771